

Remarks

Claims 59-64, 110 and 111 are amended herein. Support for the amendment of claim 59, can be found throughout the specification, such as on page 7, lines 1-15; page 24, line 15 to page 27, line 5; and Figure 5. Support for the amendment of claim 60 can be found throughout the specification, such as on page 8; page 27, line 28 to page 28, line 27; and Figures 7. Support for the amendment of claims 61-64 can be found throughout the specification, such as on page 7; page 25, line 3 to page 27, line 5; and Figures 5-6 and 8. Support for the amendment of claim 110 can be found throughout the specification, such as on page 27, line 29 to page 28, line 27, see for example, page 28, lines 5-11. Support for the amendment of claim 111 can be found throughout the specification, such as on page 28, lines 14-27.

New claims 112-118 are added herein. Support for new claims 112-115 can be found throughout the specification, such as in original claims 3, 4, 5 and 6; pages 24-27 of the specification, and figures 6-8. Support for new claims 116-117 can be found throughout the specification, such as on page 27, line 5 to page 28, line 27, see for example page 28, lines 5-11; page 13, line 17-23; and page 19, lines 7-10. Support for new claim 118 can be found throughout the specification, such as on page 24, line 15 to page 28, line 27; Figures 5-6 and 8.

Claims 67, 68, 71-78, 80-86, 88-90, 92-102 and 108 have been withdrawn from consideration by the Examiner.

Reconsideration of the present application is respectfully requested in view of the foregoing amendments and following remarks.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 59-65, 104-106, 110 and 111 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and for encompassing new matter.

The Office action alleges that there is insufficient support for a CD-146 cell that can proliferate for 140 doublings. The specification discloses that an isolated population of *ex vivo* expanded SHED cells can proliferate for 140 population doublings (see Fig. 5G-5H) and page 25, lines 1-5. This population of cells gives rise to neural cell (see page 26, line 10 to page 27,

line 5), an adipocyte (see page 26, lines 3-9), and an odontoblast (see page 25, line 22 to page 26, line 2). These limitations are provided in claim 59 as amended.

The specification also discloses that this same population of SHED cells expresses the cell surface markers STRO-1 and CD146 (see page 25, line 7). In addition, Figs. 6D and 6E illustrate that while only some of the cells express STRO-1 (see Fig. 6D and page 7, line 21), all of the cells express CD146, albeit some more strongly than others (see Fig. 6E).

Thus, although the specification does not disclose that expression of CD146 was assessed following the expansion for 140 population doublings (which the Office seems to require), the cells that initiated the culture system MUST have expressed CD146. Furthermore, the data presented in the specification documents that cells in this exact population must have undergone 140 population doublings. Thus, a cell that expressed CD146 must have proliferated for 140 population doublings. There is sufficient written description for cells that express CD146 that undergo 140 population doublings. However, to advance prosecution, the limitation that the cells express CD146 has been deleted from claim 59.

With regard to claim 61, the specification discloses an isolated population of stem cells isolated from a postnatal deciduous tooth, wherein cells in the population can proliferate for 140 population doublings. The specification further discloses that cells within this population differentiate into cells that express STRO-1, ALP, matrix extracellular phosphoglycoprotein, basic fibroblast growth factor, endostatin (see, for example, page 25, lines 14-15 and Figs. 6F to 6I). With regard to claim 62, the specification discloses that cells within this population express in the population express CBFA1, ALP, MEPE, BSP, DSPP following mineralizing induction (see, for example, page 25, lines 22-30). With regard to claim 63, the specification discloses that cells within this population express CBFA1, Osterix, Osteocalcin, or any combination thereof following induction with BMP-4 (see, for example, page 25, line 30 to page 26, line 2). With regard to claim 65, the specification discloses that the cells within this population express nestin, β III tubulin, glutamic acid decarboxylase, neuronal nuclei, glial fibrillary acidic protein, neurofilament M, 2',3'-cyclic nucleotide-3'-phosphodiesterase, or any combination thereof following neural induction (see, for example, page 26, lines 21-29). Claims 112-115 are added herein that are directed to populations that express the specific combinations of markers, as supported by original claims 3, 4, 5 and 6; pages 24-27 of the specification, and figures 6-8.

With regard to claim 60, this claim is amended to be limited to the clonal populations of stem cells, as described in the specification, such as on pages 27-28. These stem cells are from a postnatal deciduous tooth and induce formation of bone, but do not form bone, when transplanted *in vivo* (see, for example, page 28, lines 5-7). Note that this limitation is also included in claim 110. With regard to claims 110 and 111, these claims are also directed to SHED cells. The Office action confirms that the biological deposit is to the biological material identified in the application as originally filed (see page 3). These claims have been amended to be in independent form, although they are directed to SHED cells.

Claims 116-117 are added that are directed to compositions that include these cells (see page 13, lines 17-23 and page 19, lines 7-10).

Clearly there is sufficient written description for the claims as amended, and no new matter is added. Reconsideration and withdrawal of the rejection are respectfully requested. In the unlikely event that this rejection is maintained, the Examiner and the Supervisory Examiner are respectfully requested to contact the undersigned to schedule a telephone interview to expedite prosecution.

Post Filing Date Information

A copy of Huang et al., "Mesenchymal Stem Cells Derived from Dental Tissues vs. Those from Other Sources: Their Role in Biology and Role in Regenerative Medicine," Critical Reviews in Oral Biology & Medicine, J. Dent. Res. 88(9): 792-806, 2009, is attached. This review compares five different dental stem cells types, including Dental Pulp Stem cells (DPSCs, see Gronthos et al., J. Dent. Res. 81: 531-535, 2002, of record; Gronthos et al., PNAS 97: 13625-13630, 2000, of record; Shi et al., PCT Publication No. WO 02/07679, of record; Shi et al., Bone 29: 532-539, 2001, of record) and Bone Marrow Derived Mesenchymal Stem Cells (BMMSC, see PCT Publication No. WO 02/07679). As disclosed in Huang et al each type of stem cell from the dental tissue has unique characteristics. Only populations of SHED cells can proliferate for 140 population doublings and induce the formation of bone (see page 795, Table 1, and the paragraph bridging pages 795-796); no other type of dental stem cells has these characteristics.

The Examiner is requested to consider this evidence prior to the issuance of the next Office action. If the evidence must be presented in a Declaration, the Examiner and the Supervisory Examiner are respectfully requested to contact the undersigned by telephone.

Request for Rejoinder

The examiner has required restriction between product and process claims. As set forth in MPEP § 821.04, when an applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim should be considered for rejoinder. It is the Applicants' understanding that all claims directed to a nonelected process that include all the limitations of an allowable product claim will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104.

Conclusion

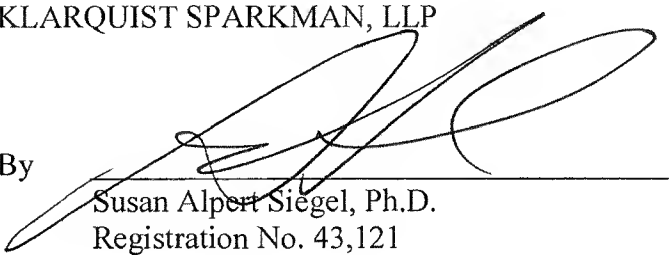
Following entry of this amendment, Applicants believe that the present claims are in condition for allowance, which action is requested. *If any issues remain prior to allowance, the Examiner and the Supervisory Examiner are formally requested to contact the undersigned prior to issuance of a final Office action, in order to arrange a telephonic interview.* It is believed that a brief discussion of the merits of the present application would expedite prosecution and allowance. This renewed request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

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